

Orientation to the Voluntary Children's Chemical Evaluation Program (VCCEP)

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**EPA/ACC Technical Workshop for the Voluntary
Children's Chemical Evaluation Program (VCCEP)**



Background

- VCCEP developed via a public stakeholder process
- VCCEP is not a testing program – hazards, exposures, and risks of chemicals to children are evaluated and if necessary information gaps are to be filled
- FR Notice announcing the “Voluntary Children’s Chemical Evaluation Program” issued December 26, 2000 (65 FR 81699)
- The Pilot attempts to define a workable common ground that meets the needs of diverse stakeholders



Key Features of the VCCEP

- Goal is publicly available data
- Strong chemical selection criteria – biomonitoring data
- Tiered testing scheme
- Implementation process builds on and models the HPV Challenge when ever possible
- Commitments made tier by tier in the Pilot



Key Features of the VCCEP (cont.)

- **Role for exposure information gathering and assessment**
- **Additional data development decisions (such as testing or exposure studies) based on whether chemical is adequately characterized given the available data**
- **Peer Consultation promotes joint stewardship of the program and a strong science foundation**



Initial VCCEP Implementation as a Pilot

- **Gain insight into how best to design and implement VCCEP in its final form**
- **Test performance of tiered approach and Peer Consultation process and identify potential efficiencies**
- **Evaluation of the pilot at 3 and 6 years**



Sponsor Responsibilities in the VCCEP Pilot

- **Cooperate with other potential sponsors**
- **Preparation of Tier 1 data:**
 - **Hazard Assessment**
 - **Exposure Assessment**
 - **Risk Assessment**
 - **Tier 2 Data Needs Assessment**
- **Make data publicly available**
- **Participation in Tier 1 Peer Consultation**
- **Consider Tier 2 Sponsorship if necessary**



VCCEP Test Battery and Tiers

- Tiered battery:
 - 1st Tier HPV Challenge human health studies plus existing higher tier studies
 - 2nd and 3rd Tiers provide for an in-depth assessment
- Tiers include exposure assessment – this was a key feature in the evolution of VCCEP



Exposure Assessment

- Transparency and completeness – sponsors should consider to what degree the potential exposures to children (and prospective parents in certain situations) from environmental releases and uses of the chemical have been accounted for and addressed
- Biomonitoring data used for chemical selection contribute to an overall assessment
 - Strong qualitative evidence that human exposure has occurred
 - Given the concerns about the quality of some the biomonitoring data, it needs to be supplemented
 - Refuting biomonitoring data is not sufficient



Exposure Assessment (Cont.)

- EPA will work with stakeholders to develop a template that sponsors can use to provide exposure information – exposure “Robust Summaries”
- Use EPA’s “*Exposure Assessment Guidelines*” and other existing procedures and guidance such as “*Child Specific Exposure Factors Handbook*”
- Depth of exposure information increases with each tier:
 - Tier 1: screening level data, including conservative quantitative estimates of exposures
 - Tiers 2 and 3: advanced assessments using exposure studies, monitoring data, and modeling



Exposure Assessments

Should Include:

- **All manufacturing and processing activities that can lead to exposure to children and prospective parents when relevant**
- **All industrial, commercial, and consumer uses leading to exposure to children**
- **Measures or estimates of environmental releases**
- **Physical chemical properties and environmental fate**
- **Activity patterns, age ranges and sub populations associated with activities**
- **Estimates of extent, duration and frequency of exposures**



Exposures Outside the Chain of Commerce

- For Tier 1, sponsors should develop a screening level assessment of readily available exposure information, including data on exposures outside the chain of commerce – put totality of exposures into context
- Beyond Tier 1, EPA stands ready to assist sponsors in developing more sophisticated exposure assessments addressing outside the chain of commerce exposures by engaging other EPA offices, Federal agencies, companies and trade associations



Peer Consultation

- Forum for scientists and experts from stakeholder groups to exchange scientific views on sponsor's assessments and recommended data needs
- Not a consensus based approach
- Independent third party will compile results and comments from the Peer Consultation and draft a report to be made available to all participants



Peer Consultation (cont.)

- **Standard used to evaluate sponsor's submissions:**

Are data sufficient to adequately characterize the risks of the chemical to children?

- **If EPA's approach differs substantially from that indicated by the third party's report, EPA will provide a supporting rationale indicating the basis for its approach**



For more information about VCCEP and its pilot (including past Federal Register Notices, documentation of the stakeholder involvement process, chemical selection methodology, guidance materials and other technical materials) see:

www.epa.gov/chemrtk/childhlt.htm

